THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 25

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte RICHARD COTTER and HUGH TUCKER

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Appeal No. 93-4191
Application 07/831,627[1]

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ON BRIEF

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Before WILLIAM F. SMITH, ELLIS and WEIMAR, **Administrative Patent Judges**.

ELLIS, **Administrative Patent Judge**.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 1 through 16, which are all of the claims pending in the application. Claims 1 and 6 are illustrative of the subject

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[1] Application for patent filed February 6, 1992. According to the appellants, this application is a continuation of Application 07/506,938, filed April 10, 1990, now abandoned.

matter on appeal and read as follows:

1. A method for maintaining gastrointestinal integrity and function in a patient whose gut bacteria flora is modified, reduced, or eliminated so as to impair its ability to provide short chain fatty acids as an energy source comprising:

administering to the patient a composition including a lipid source that upon hydrolysis yields short chain fatty acids.

6. The method of Claim 1 wherein the composition that upon hydrolysis yields short chain fatty acids includes at least one lipid source chosen from the group consisting or triglyceride, diglyceride, and monoglyceride.

The references relied on by the examiner are:

Ingenbleek et al. (Ingenbleek)	4,526,793	July 2, 1985
Blackburn (Blackburn `197)	4,528,197	July 9, 1985
Nelson et al. (Nelson)	4,665,057	May 12, 1987
Cotter et al. (Cotter `807)	4,678,807	July 7, 1987
Ward et al. (Ward)	4,678,808	July 7, 1987
Simko	4,690,820	Sep. 1, 1987
Blackburn et al. (Blackburn `062)	4,703,062	Oct. 27, 1987
Jandacek et al. (Jandacek)	4,753,963	June 28, 1988

Bistrian et al. (Bistrian)	4,810,726	Mar. 7, 1989
Cotter et al. (Cotter `098)	4,920,098	Apr. 24, 1990
Babayan et al. (Babayan)	4,952,606	Aug. 28, 1990
Klemann et al. (Klemann)	4,992,292	Feb. 12, 1991

Cotter et al. (Cotter ‘89), “Competitive effects of long-chain-triglyceride emulsion on the metabolism of medium-chain-triglyceride emulsions”, **Am. J. Clin. Nutr**., Vol. 50, pp. 794-800 (1989).

Johnson et al. (Johnson), “Medium-chain-triglyceride lipid emulsion: metabolism and tissue distribution”, **Am. J. Clin. Nutr.**, Vol. 52, pp. 502-508 (1990).

A reference relied on by this merits panel is:

The Merck Manual, “Gastrointestinal Disorders”, Sixteenth Edition, pp. 832-34 (1992).

Claims 1 through 16 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as unpatentable over Cotter (‘89), Babayan, Cotter (‘098), Cotter (‘807), Ward, Blackburn (‘197), Blackburn (‘062), Ingenbleek, Nelson, Simko, Jandacek, Bistrian, Klemann, and Johnson.

We **reverse**.

In the case before us we agree with the appellants that

the examiner's rejection is less than a model of clarity. Although a plethora of references have been cited by the examiner as either anticipating or rendering obvious the claimed method, no where in the Answer does the examiner identify the teachings within the references on which his findings or conclusion are based. Moreover, we find the examiner's reading of the treatment of the specified patient group out of the claims to constitute legal error.[2] Accordingly, the rejection is reversed.

Other Issues

Upon return of this application to the corps, the examiner should consider the patients described in applied prior art and determine whether they would include patients

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[2] We refer to the examiner's statement on p. 7, para. 4 of the Answer that:

> [a] preamble is generally not accorded any patentable weight, by the U.S.P.T.O., when it merely recites a purpose for carrying out the process. [Citations omitted.] A preamble is of no patentable import when the claimed process relates to a method of using rather than a method of making. [Citations omitted.]

"whose gut bacteria flora is modified, reduced, or eliminated so as to impair its ability to provide short chain fatty acids as an energy source." According to the specification, this physiological state can occur, but is not limited to, the treatment of patients with antibiotics, chemotherapy, or radiation. Specification, p. 2, lines 2-4. In this regard, we direct attention to the teachings of Cotter '807 that triglycerides of medium chain fatty acids (MCTs), which include triglycerides of C_6 fatty acids, be administered to patients with organ transplants, Crohn's disease, etc. With respect to Crohn's disease, for example, The Merck Manual[3] states that immunosuppressive drugs are effective to treat some aspects of the disease, and that "[b]road spectrum antibiotics that are active against enteric gram-negative and anaerobic flora may be of benefit in reducing disease activity in some patients but are most effective for suppurative complications (e.g., abscess infected fistula)." Thus, it

[3] The Merck Manual, Sixteenth edition, pp. 832-34 (1992), copy attached to this decision. We recognize that this edition is not prior art against the present claims. The examiner should perform the necessary investigation to determine if similar knowledge is contained in the prior art.

appears that some of the patients described by Cotter ‘807, might be within the breadth of the claims on appeal. However, the burden is on the examiner, and not this merits panel, to make such findings. In the event that the examiner does determine that the patients described by Cotter ‘807, or any other prior art reference, are encompassed by the claims, he must clearly state, on the record, the factual basis for any such findings and provide the appellants with a fair opportunity to respond.

Alternatively, the examiner might consider whether the specification would have enabled one skilled in the art to “make and use” the claimed method as required by 35 U.S.C. § 112, first paragraph. The examiner should consider whether the specifi-cation would have enabled one skilled in the art to determine which patients are encompassed by the claims in the first instance. That is, the examiner might consider whether the teachings of the specification would have enabled those skilled in the art, to identify those patients in which the “gut bacteria flora is modified, reduced, or eliminated so as to impair its ability to provide short chain fatty acids as

an energy source." For example, will any patient taking antibiotics be afflicted with the claimed physiological condition, or just those patients taking certain antibiotics? Is there a diagnostic assay available to those skilled in the art to identify the claimed patient type?

In addition, the examiner might consider whether the specification would have enabled the claimed method for maintaining gastrointestinal integrity by administering a composition comprising a lipid source that upon hydrolysis yields short chain fatty acids. For example, it appears that the examples in the specification only disclose compositions which comprise ***preformed*** short chain fatty acids (SCFA) and, not compositions which comprise a lipid source which upon hydrolysis yields short chain fatty acids.[4] Specification, Examples 1

[4] If the medium chain triglycerides (MCTs) used in the exemplified compositions hydrolyze to form SCFAs ***in vivo***, then it would appear that the compositions described in references such as Cotter '807 which contain MCTs, especially those described as triglycerides of C_6 fatty acids, will of necessity hydrolyze ***in vivo*** to form SCFAs. Thus, the issue becomes whether the prior art teaches or suggests administering MCTs to patients meeting the requirements of claim 1.

through 4, pp. 5-11. Thus, the examiner might consider whether

the specification description of the nutrient compositions would have enabled one skilled in the art to “make and use” the claimed lipid source.

Finally, assuming arguendo the specification does enable the use of a composition comprising the appropriate lipid source, the examiner should consider whether it would have enabled one skilled in the art to determine whether said compositions are capable of effective maintainance of gastrointestinal integrity and function. That is, it does not appear that the specification provides any assays or other indicia by which the effects of administering the claimed composition can be monitored. Are breakdown products to be measured in the patient’s serum, urine, etc., or are there physiological changes which can be observed in the patient in which the treatment was effective?

The examiner is cautioned that should he determine that

the specification fails to satisfy the requirements of 35 USC § 112, first paragraph, he has the initial burden of providing a reason based on technical reasoning and/or objective evidence as to why one skilled in the art would not have been able to make and use the claimed invention without undue experimentation. ***In re Goodman***, 11 F.3d 1046, 1050, 29 USPQ2d 2010, 2013 (Fed. Cir. 1993); ***In re Wands***, 858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988); ***In re Marzocchi***, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

The decision of the examiner is reversed.

REVERSED

William F. Smith)
Administrative Patent Judge)
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Joan Ellis) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
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